K 120814
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SEP 6 2012

Section 3: 510(k) Summary
(Per 21 CFR 807.92)

Establishment Information:	Aponos Medical Corp. is located at: Unit 7, RT 125 Kingston, NH 03848

The Company intends to register with FDA upon receipt of clearance of this 510(k) Notice, and prior to initiating distribution of any products. The manufacturing of the Padlock Clip™ device will be carried out by Aponos at their facility at the same location.

General Company Information:	Aponos Medical Corp. Denis LaBombard CTO 17 Route 125, Bldg. A #7 Kingston, NH 03848 Phone: 603-347-8229 Fax: 978-945-6197
Official Correspondent:	John Fee VP of Quality and Regulatory Affairs Phone: 603-702-0066 Email: tjfee@aol.com
Date Prepared	September 5, 2012
General Device Information:	
Product Name:	Padlock Clip™ (Padlock-G Clip)
Common Name:	Ligation clip
Classification Name:	ligator, esophageal
Regulation Number:	21 CFR 876.440
Product Codes:	MND and FHN. Class II device
Predicate Device(s)	OVESCO Endoscopy AG OTSC™ 'Over-The-Scope-Clipping System Set including the OTSC™ Reloader. 510k – K101428

510(k) Number - K120814

Device Name: Aponos Medical, Padlock Clip™

Indications for Use:

The Aponos Medical Padlock Clip™ is indicated for use in flexible endoscopy and for the compression of tissue in the gastrointestinal tract, for hemostasis or for treating lesions of the wall of gastrointestinal organs.

The Padlock Clip is indicated for clip placement within the Gastro-intestinal (GI) tract for the purpose of:

- Endoscopic marking of lesions.
- Hemostasis for
  - Mucosal/Sub mucosal defects
  - Bleeding Ulcers
  - Arteries <2mm
  - Polyps <1.5cm diameter
  - Diverticula in the Colon
- Closure of GI tract luminal perforations < 20mm that can be treated conservatively.

Description of Device:
The Padlock Clip™ ligation clip consists of a preloaded, radiopaque, single use, coin sized ligation clip made of superelastic shape memory alloy (Nitinol®) for tissue approximation device with opening sizes of 6 to 24mm on a flexible delivery system.

Compliance with Special Controls:
Aponos Medical is unaware of any performance standard regarding this type of device that has been promulgated by FDA.

Performance Standards:
Aponos Medical has conducted appropriate testing and has determined that the Padlock Clip ligation clip is acceptable for its intended use.
Section 9 includes completed Standard Data Reports (Form FDA 3654) for these standards, as well as those relevant to sterilization, referenced in this submission.

Technological Characteristics Summary:
The Padlock Clip™ system set is substantially equivalent to the predicates, as they have similar technological characteristics. The results of animal and performance testing show no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2015

Aponos Medical Corp.
John Fee
VP of Quality & Regulatory Affairs
16 Hillside Road
Kingston, NH 03848

Re: K120814
Trade/Device Name: Aponos Medical, Padlock Clip™
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: PKL
Dated (Date on orig SE ltr): August 20, 2012
Received (Date on orig SE ltr): August 21, 2012

Dear John Fee,

This letter corrects our substantially equivalent letter of September 6, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number - K120814

Device Name: Aponos Medical, Padlock Clip™

Indications for Use:

The Aponos Medical Padlock Clip™ is indicated for use in flexible endoscopy and for the compression of tissue in the gastrointestinal tract, for hemostasis or for treating lesions of the wall of gastrointestinal organs.

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  - Arteries <2mm
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  - Diverticula in the Colon
- Closure of GI tract luminal perforations < 20mm that can be treated conservatively.

Prescription Use ____X____ **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120814